IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ALAN J. CHESKIEWICZ, a minor, by his parents and natural guardians, ALLAN J. CHESKIEWICZ and RITA M. CHESKIEWICZ, and ALLAN J. CHESKIEWICZ and RITA M. CHESKIEWICZ, in their own right, Plaintiffs, v. AVENTIS PASTEUR, INC., individually and as successor in interest to CONNAUGHT LABORATORIES, INC., PASTEUR MERIEUX and PASTEUR MERIEUX CONNAUGHT; GLAXOSMITHKLINE, individually and as successor in interest to SMITHKLINE BEECHAM CORP.; WYETH, individually and as successor in interest to AMERICAN HOME PRODUCTS, CORP. d/b/a WYETH, WYETH LABORATORIES, WYETH-AYERST, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES AND LEDERLE LABORATORIES; MERCK & COMPANY, INC.; PFIZER, INC., a subsidiary of WARNER LAMBERT, individually and as a successor in interest to PARKE-DAVIS, INC.; ABBOTT LABORATORIES; ELI LILLY & COMPANY; SIGMA-ALDRICH, INC.; AMERICAN INTERNATIONAL CHEMICAL, INC.; and JOHN DOES 1-10, Defendants.	Civil Action No. 02-3583 (Judge Norma L. Shapiro)

O R D E R

AND NOW, this _____ day of _____, 2002, upon consideration of Plaintiffs' Motion for Remand and Defendants' Opposition thereto,

IT IS HEREBY ORDERED that Plaintiffs' Motion for Remand is DENIED.

BY THE COURT:

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Norma L. Shapiro, U.S.D.J.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ALAN J. CHESKIEWICZ, a minor, by his parents and natural guardians, ALLAN J. CHESKIEWICZ and RITA M. CHESKIEWICZ, and ALLAN J. CHESKIEWICZ and RITA M. CHESKIEWICZ, in their own right, Plaintiffs, v. AVENTIS PASTEUR, INC., individually and as successor in interest to CONNAUGHT LABORATORIES, INC., PASTEUR MERIEUX and PASTEUR MERIEUX CONNAUGHT; GLAXOSMITHKLINE, individually and as successor in interest to SMITHKLINE BEECHAM CORP.; WYETH, individually and as successor in interest to AMERICAN HOME PRODUCTS, CORP. d/b/a WYETH, WYETH LABORATORIES, WYETH-AYERST, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES AND LEDERLE LABORATORIES; MERCK & COMPANY, INC.; PFIZER, INC., a subsidiary of WARNER LAMBERT, individually and as a successor in interest to PARKE-DAVIS, INC.; ABBOTT LABORATORIES; ELI LILLY & COMPANY; SIGMA-ALDRICH, INC.; AMERICAN INTERNATIONAL CHEMICAL, INC.; and JOHN DOES 1-10, Defendants.	Civil Action No. 02-3583 (Judge Norma L. Shapiro)

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR REMAND

Plaintiffs' Motion for Remand should be denied. This Court has jurisdiction to hear this case pursuant to 28 U.S.C. § 1332, because the only non-diverse defendants -- vaccine manufacturers Aventis Pasteur and GlaxoSmithKline -- are sham defendants. Pursuant to the National Childhood Vaccine Injury Act (the "Vaccine Act" or the "Act"), plaintiffs are barred

from bringing a civil action against the vaccine manufacturer defendants because they have not first filed a petition for compensation under the Act. Under the Vaccine Act, plaintiffs have no colorable cause of action against these vaccine supplier defendants and, therefore, they should be deemed to be "fraudulently joined" and their citizenship disregarded under 28 U.S.C. § 1332.[1]

Joinder is considered "fraudulent" for purposes of diversity jurisdiction when, as here, "there is no reasonable basis in fact or colorable ground supporting the claim against the [non-diverse] defendant." Boyer v. Snap-On Tools Corp., 913 F.2d 108, 111 (3d Cir. 1990); In Re: Diet Drugs, 1999 WL 554584, at *2.[2] It is well established that the citizenship of fraudulently joined parties is disregarded in determining diversity jurisdiction for purposes of removal. See Illinois Cent. R.R. Co. v. Sheegog, 215 U.S. 308, 316 (1909) ("[I]f it appears that the joinder was fraudulent, as alleged, it will not be allowed to prevent the removal"); In Re: Diet Drugs Prods. Liab. Litig., 1999 WL 554584, at *2 (E.D. Pa.) ("The doctrine of fraudulent joinder allows the court to disregard parties that are fraudulently joined in a civil action when determining whether complete diversity of citizenship exists"). Fraudulent joinder is determined by the causes of action contained in "the plaintiffs' pleading at the time of the petition for removal." Pullman Co. v. Jenkins, 305 U.S. 534, 537 (1939).

Claims for alleged vaccine-related injuries cannot be asserted against vaccine manufacturers in court until Plaintiffs have first filed a petition for compensation under the Act. 42 U.S.C. § 300aa-11(a)(2)(A). Plaintiffs do not claim to have ever filed a petition for

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1 Citizenship, if any, of "John Does 1-10" must also be disregarded. 28 U.S.C. § 1441(a).

2 Under such circumstances, defendants as to whom there is diversity are entitled to removal even if -- as here -- the claims against the removing defendants are equally devoid of colorable merit. See, e.g., Ritchey v. Upjohn Drug Co., 139 F.3d 1313, 1320 (9th Cir.), cert. denied, 525 U.S. 963 (1998).

compensation for alleged vaccine-related injuries as required. Plaintiffs have no remotely colorable cause of action against the sham defendants pursuant to the unambiguous provisions of Vaccine Act and their citizenship must be disregarded.

I. SUMMARY OF ARGUMENT

Three things should be clear. First, all three plaintiffs (Alan, Rita, and A.J.) complain about injuries "traceable to vaccinations"[3] administered to A.J. Second, the Vaccine Act requires that a civil action alleging such "vaccine-related injuries" must be dismissed outright if the plaintiff has not first filed a petition for compensation in the Federal Court of Claims (the "Vaccine Court"). Third, as recognized by the Vaccine Court, the Secretary of Health and Human Services ("HHS Secretary"), the Department of Justice, and the one federal court to decide the issue, claims concerning the thimerosal component (or any other component) in vaccines do not come within the "adulterant or contaminant" exception to the Vaccine Act. Because the Act applies and requires the dismissal of plaintiffs' claims against the vaccine manufacturers Glaxo and Aventis, the claims are "sham" and Glaxo and Aventis must be deemed fraudulently joined.

Plaintiffs do not contest that their claims concerning thimerosal are "traceable" to A.J.'s vaccinations; the thimerosal preservative, after all, was in the vaccines. Nor do plaintiffs claim that they have ever filed a petition for compensation in the Vaccine Court on behalf of A.J.; indeed, they admit they have not done so and assert that the Vaccine Act's statute of limitations now bars filing a petition. Plaintiffs stake everything on their unsupportable assertion that thimerosal is an "adulterant or contaminant" within the meaning of the Act.

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[3] Shalala v. Whitecotton, 514 U.S. 268, 269 (1995) (explaining that the Vaccine Act applies to claims "traceable to vaccinations").

Plaintiffs should know better. Their Memorandum expresses a familiarity with the course of the litigation in other courts, so plaintiffs are not ignorant of the fact that the Vaccine Court is currently exercising jurisdiction over identical claims under the Vaccine Act; that the HHS Secretary has declared unequivocally that the Act applies to claims concerning thimerosal-containing vaccines; that the Department of Justice has gone into federal court in a similar case to file a "Statement of Interest" of the United States explaining that the arguments made by plaintiffs are "erroneous"; and that federal courts in Texas, Florida and Mississippi have recognized that the Act applies. Plaintiffs turn a blind eye to this authority, however, because there is no answer to it. If met head-on, the only reasonable conclusion that can be drawn is that the Vaccine Act applies and requires dismissal of plaintiffs' claims.

Consider what plaintiffs refuse to address:

The Vaccine Court. In the real world, the theoretical question of whether the Vaccine Act applies to claims concerning thimerosal-containing vaccines translates into the practical question of whether the Vaccine Court will exercise jurisdiction over such claims or reject them. And the Vaccine Court has already answered that practical question. In a "Statement of Interest" filed in March of 2002 in another case in which plaintiff attempted to invoke the "adulterant or contaminant" exception, the HHS Secretary noted that the Vaccine Court was "already exercising jurisdiction over more than 60 cases alleging injury from thimerosal."[4] And in June, the Office of Special Masters in the Vaccine Court issued an order in each of the more than 300 thimerosal cases now pending stating its intention "to set forth a meaningful time schedule ***for resolving these cases***."[5] There is no reasonable possibility that the

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[4] Statement of Interest Submitted by the United States Department of Health and Human Services, King v. Aventis Pasteur, Inc., CV 01-1305-AS (D. Ore.) (attached as Exhibit 1), p. 3.

[5] See, e.g., Verdon v. Secretary of HHS, 0-208V (June 5, 2002) (attached as Exhibit 2).

Pennsylvania state court (or any court) could find that the Vaccine Act does not apply and the Vaccine Court will not exercise jurisdiction when it is, in fact, already doing so in numerous other indistinguishable cases.

The HHS Secretary. Over 30 years ago, long before this litigation, the federal government recognized that vaccines contain a number of ingredients, including preservatives. By regulation, issued after notice and comment, the HHS Secretary defined preservatives as "constituent materials" of vaccines in 21 C.F.R. § 610.15. Section 610.15 comes under Subchapter F – Biologics, vaccines being a "biological" product, not a pharmaceutical. Section 610.15 is captioned "Constituent materials," and its first subsection reads: "(a) Ingredients, ***preservatives***, diluents, [and] adjuvants." 21 CFR § 610.15 (emphasis added).[6] It follows that, if preservatives (like thimerosal) are "constituent materials" of vaccines, they cannot be "adulterants or contaminants," which, by definition, are something extraneous that find their way into a vaccine by criminal tampering or sloppy manufacturing practices. Applying § 610.15, the HHS Secretary has publicly announced: "Because thimerosal is not an adulterant to or a contaminant of vaccines, individuals who have claims relating to thimerosal in vaccines . . . must first file the claim with the [Vaccine Court] before pursuing any other civil litigation."[7] As the public official charged with the administration and interpretation of the Act, the HHS Secretary's determination, grounded in § 610.15, that the Vaccine Act covers claims concerning vaccine preservatives (including thimerosal) is controlling authority. And because the HHS Secretary's

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6 A copy of this regulation, never challenged or questioned for more than three decades, is attached as Exhibit 3.

7 United States Department of Health and Human Services, Health Resources and Services Administration, "Commonly Asked Questions About the National Vaccine Injury Compensation Program," available at http://www.hrsa.gov/osp/vicp/qanda.htm#17 (May 2002). The relevant printout from this site is attached as Exhibit 4.

determination is controlling as a matter of law, there is no possibility that the Pennsylvania state court (or any court) could find that the Vaccine Act does not apply.

Department of Justice. The sovereign immunity doctrine does not require a narrow reading of the Act that would exclude plaintiffs' claims, for the doctrine does not even come into play. Sovereign immunity belongs to the sovereign and must be invoked by the sovereign. Here, the sovereign has taken the very unusual step of filing a Statement of Interest in a similar case in order to say this: "Plaintiffs cannot avoid the exclusive jurisdiction of the Program by ***erroneously arguing that thimerosal is an adulterant or contaminant***. The plain language of the statute and the determinations that have been made by the HHS Secretary demonstrate that ***their argument is fundamentally incorrect and without merit***."[8] Again, there is no possibility that a Pennsylvania state court (or any court) could rely on the operation of the sovereign immunity doctrine to construe the Vaccine Act narrowly, because the United States has not only not invoked the doctrine, but has affirmatively taken the position that the Act covers vaccines and all their components, including thimerosal.

The Federal Courts. Plaintiffs' Memorandum ("Pl. Mem.") was filed on June 27, but it does not mention the trilogy of decisions entered on May 7-8 by the United States District Court for the Southern District of Texas. That court held that the Vaccine Act covers claims for injuries allegedly caused by thimerosal and dismissed the plaintiffs' claims for failure to first file a petition with the Vaccine Court.[9] Rejecting the argument -- identical to that offered by

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8 Statement of Interest (Exhibit 1), p. 20-21 (emphasis added).

9 See O'Connell v. American Home Prods. Corp., Civil Action No. G-02-184 (S.D. Tex. May 7, 2002); Blackmon v. American Home Prods. Corp., Civil Action No. G-02-179 (S.D. Tex. May 8, 2002); and Owens v. American Home Prods. Corp., 2002 WL 992094 (S.D. Tex. May 8, 2002). A copy of each of these decisions is attached as Exhibit 5. Because each of these decisions is premised on the same legal analysis, and to avoid confusion with the United States Court of Appeals decision in O'Connell v. Shalala, 79 F.3d 170 (1st Cir. 1996), citations to the District Court's legal analysis will be limited to that in the Owens decision which is reported in WestLaw.

plaintiffs here -- that claims concerning thimerosal-containing vaccines cannot come under the Act because the preservative thimerosal is an "adulterant or contaminant" added to vaccines, the court said: "***the language of the Vaccine Act unambiguously and specifically indicates that injuries caused by vaccines preservatives (i.e. thimerosal) are within its scope,*** [and] ***it is clear that Congress has spoken to the precise question at issue***."[10] Indeed, the court concluded, such injuries "cannot be 'thimerosal-related' without being 'vaccine-related' [under the Act] as well."[11] Moreover, although finding that the language of the Act unambiguously covers injuries allegedly caused by the thimerosal component of vaccines, the court noted that, had Congressional intent not been so clearly expressed, it would have been bound to adopt the determination made by the HHS Secretary.[12]

Plaintiffs cite three decisions remanding thimerosal cases (Pl. Mem. at 14), but do not examine or discuss the reasoning of those decisions, for they cannot withstand examination. The three decisions are wrongly decided, and plainly so. Inexplicably, the decisions fail to address – indeed, do not even acknowledge – that the Vaccine Court is currently exercising jurisdiction over numerous cases; that the law has defined preservatives (like thimerosal) as "constituent materials" of vaccines for 30 years; that, in reliance on this legal definition that pre-existed the Vaccine Act, the HHS Secretary has determined that thimerosal-related claims necessarily fall under the Act; and that established precedent dictates that the HHS Secretary's interpretation of the Act is controlling. When one confronts these facts and authorities, as the Texas federal court did, the only conclusion is that the Act "unambiguously" applies. There is

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10 Owens at 9, n.11.

11 Owens at 9.

12 See Owens at 9, n.11 (citing Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., *supra*, at 843-44 (1984)).

no colorable claim against vaccine manufacturers and, thus, that plaintiffs' claims here against Glaxo and Aventis are sham.

II. PROCEDURAL AND STATUTORY BACKGROUND

A. The Complaint

On May 10, 2002, plaintiffs commenced this action in the Court of Common Pleas of Philadelphia County, Pennsylvania, on behalf of a minor child "A.J." who, from May 1994 through December 1995, allegedly received several childhood vaccinations containing Thimerosal, a preservative used to prevent bacterial and fungal contamination. Plaintiffs allege that their child suffered neurological and neurodevelopmental injuries as a result of the vaccinations. The Complaint seeks compensatory and punitive damages for these vaccine-related injuries both on behalf of the child and by his parents in their own capacities for medical expenses allegedly incurred on behalf of their son.

B. The National Childhood Vaccine Injury Act

Because plaintiffs allege injuries "traceable to vaccinations,"[13] and vaccinations involving vaccines listed on the Vaccine Injury Table, this case implicates the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 *et seq*. When Congress passed the Vaccine Act in 1986, it recognized that "[v]accination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. Rep. No. 99-908 at 4 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6345. At the same time, Congress recognized that the cost of litigation initiated on behalf of children claiming injuries traceable to vaccination had resulted in a significant reduction in the number of manufacturers willing to sell childhood vaccines. Id.

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[13] See Shalala v. Whitecotton, 514 U.S. 268,269 (1995) (the Act applies to "injuries and deaths traceable to vaccinations").

Congress was particularly concerned that the costs of litigation would lead to a dwindling supply of vaccines. Id. at 6-7, reprinted in 1986 U.S.C.C.A.N. at 6347-48. See also Reed v. Connaught Labs., Inc., 48 Pa. D. & C.3d 400, 404 (1987) (recognizing that the Vaccine Act resulted from inadequacies of the traditional tort system, both for injured persons and manufacturers).

Because of its "real concern about the future of Federal immunization initiatives," and to safeguard the national vaccine supply, Congress included in the Vaccine Act a compensation program to provide claimants a just and efficient remedy while also protecting vaccine manufacturers from excessive litigation costs. 46 H.R. Rep. No. 99-908 at 4 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6345; Schafer v. American Cyanamid Co., 20 F.3d 1, 2-3 (1st Cir. 1994). Claims for compensation are (i) initiated by petition (ii) against the HHS Secretary (iii) in the Vaccine Court. Compensation awards are paid from a fund generated by an excise tax on vaccines. The new system was intended to depart from the "traditional tort system," which posed threats to the national vaccine supply. O'Connell v. Shalala, 79 F.3d 170, 173 (1st Cir. 1996).

Congress understood that this new remedial system for vaccine injuries would not achieve its laudable goals if the system were optional and therefore prohibited any person from bypassing the Vaccine Act:

> ***No person may bring a civil action for damages*** in an amount greater than $1,000 . . . against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury . . . ***unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury***. . . .

42 U.S.C. § 300aa-11(a)(2)(A) (emphasis added). The statute's meaning is clear. "Simply put, individuals who qualify as Program claimants ***must*** file petitions in the Vaccine Court in order to pursue any vaccine-related claims at all." Owens, *supra*; Harmon v. Borah, 720

A.2d 1058, 1062 (Pa. Super. Ct. 1998) ("[B]efore an injured person files a civil action, he or she must file a petition with the United States Court of Federal Claims.").[14]

Courts have strictly applied the letter and intent of § 300aa-11(a)(2)(B). The Southern District of Texas recently dismissed the claims of minor plaintiffs in three cases based on allegations essentially identical to those in this case where the plaintiffs failed to file a petition in Vaccine Court prior to commencing a civil suit. Owens, *supra*; O'Connell, *supra*; Blackmon, *supra*.[15] The claims at issue in this case are likewise clearly covered by the Vaccine Act and plaintiffs' attempts to characterize them otherwise to evade the Vaccine Act ignores precedent and contravenes controlling authority.

III. ARGUMENT

A. The Vaccine Act Applies To Claims Concerning Thimerosal-Containing Vaccines

Plaintiffs concede that the Vaccine Act prohibits a civil action for damages arising from a vaccine-related injury unless a petition for compensation has first been filed in the Vaccine Court. They further concede that the vaccines administered to A.J. are listed on the Vaccine Injury Table (and, thus, are vaccines to which the Act applies). And they concede that they have not filed a petition for compensation in the Vaccine Court. But plaintiffs contend that

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[14] The legislative history confirms the Act's plain meaning, showing that Congress intended that claimants must first seek redress under the Act: "***All individuals*** injured by a vaccine administered after the date of enactment of the legislation are required to go through the compensation program" before proceeding with ***any*** litigation against a manufacturer. H.R. Rep. No. 99-908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6344 (emphasis added).

[15] The Court in these Texas cases denied the motion to dismiss the parent-plaintiffs' consortium claims. No such claims are asserted in the Complaint pending in this Court. Here, the parents seek only to recover medical expenses incurred on behalf of their son. Such a claim must be brought under the terms of the Vaccine Act. See, e.g., Strauss v. American Home Prods. Corp., Civil Action No. G-02-226 (S.D. Tex. June 11, 2002), at 5, n.8, attached as Exhibit 6.

they are exempt from the Act because thimerosal is "an adulterant or contaminant added to the vaccines that were administered to A.J." Pl. Mem. at 10.

Plaintiffs' reasoning -- unsupported by any authority -- goes like this: thimerosal (i) is a preservative that was added to vaccines and (ii) therefore should be considered a "separate product" and (iii) not itself a vaccine. Because (iv) it is not a vaccine and (v) not therefore on the Vaccine Injury Table, the Vaccine Act cannot possibly apply. And because it is (vi) allegedly injurious, it must be an adulterant or contaminant within the meaning of the Act.

There is no authority to support plaintiffs' contention. Indeed, every authority rejects it. First and foremost, it is contrary to the regulatory law in this area, which for 30 years has defined the preservatives in vaccines as "constituent materials" of vaccines, the very opposite, in other words, of adulterants/contaminants, which are not "constituent" elements, but "extraneous" elements. See 21 C.F.R. § 610.15. The HHS Secretary, who is responsible for administering the Act, has determined that "[c]omponents, such as thimerosal, that are added to microorganisms to create vaccines ***cannot and should not be considered adulterants or contaminants***," adding that "[i]nstead, preservatives and components such as thimerosal should be considered one of several elements that comprise vaccines. . . ." HHS Website, Exhibit 4. The Department of Justice on behalf of the HHS Secretary has described plaintiffs' argument as "erroneous," "fundamentally incorrect," and "without merit." Statement of Interest at 20-21 (Exhibit 1). And faced with the same argument less than two months ago, the federal court in Texas held that "***the language of the Vaccine Act unambiguously and specifically indicates that injuries caused by vaccine preservatives (i.e., thimerosal) are within its scope***, [and] it is clear that Congress has spoken to the precise question at issue." Owens, *supra*.

Punctuating what is already an emphatic rejection of plaintiffs' assertion is the action of the Vaccine Court itself. Since the passage of the Act, the Court has repeatedly said that the Act applies to claims concerning vaccine components. There are numerous, virtually identical thimerosal-related cases now pending in the Vaccine Court, which has just declared its

intention to establish "a meaningful time schedule ***for resolving these cases***." See, Verdon, *supra*, Exhibit 2.

The fact that thimerosal is a preservative, not *per se* a "vaccine" (and not independently listed on the Vaccine Injury Table), is immaterial for two reasons – one factual and one legal. First, it can be said of ***every*** constituent biological and chemical component – even of the toxoid itself – that it alone is not the vaccine. As the HHS Secretary has explained, "at no time since Edward Jenner['s creation of the small pox vaccine] have vaccines been solely the relevant microorganisms."[16] Rather, the vaccine is, in the vernacular, the "brew" of biological ***and*** chemical components, or the "suspension" made up of those components. See Owens at 7-8.[17]

Whether the Act applies to a particular claim does not turn on whether the particular biological or chemical component that may be singled out as injurious is listed on the Vaccine Injury Table; rather, whether the Act applies depends on whether the vaccine administered to the plaintiff is listed. Here, plaintiffs do not contend that A.J. was administered any vaccines other than ones listed on the Vaccine Injury Table. He allegedly received the standard course of childhood immunizations, all of which are listed vaccines.

That thimerosal is a component (in plaintiffs' terms, "a separate product") is also immaterial because the law defines preservatives as "constituent materials" of vaccines. Long before the plaintiffs filed their Complaint, the federal government recognized that vaccines contain a number of ingredients, including preservatives. By regulation, issued after notice and

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16 Statement of Interest at 3, n.2 (Exhibit 1).

17 Plaintiffs acknowledge that a vaccine is defined as a "preparation" (Pl. Mem. at 10), but miss the significance of the term, which denotes that a vaccine is the sum of many components, which preserve the vaccine, prevent bacterial growth, maintain the vaccine's effectiveness during storage, and stabilize the vaccine. In short, the definition of "vaccine" does not indicate "that a vaccine is comprised of microorganisms alone." Owens at 8.

comment, the governing federal agency defined preservatives as "constituent materials" of vaccines. 21 C.F.R. § 610.15 (Exhibit 3). It follows from this regulation that thimerosal cannot be considered an "adulterant" or "contaminant" for the Federal Circuit has held that the "adulterant or contaminant" exception "refers only to 'intentionally added' ***extraneous material***." Amendola v. Sec'y of HHS, 989 F.2d 1180, 1186 (Fed. Cir. 1993) (emphasis added). An "extraneous material" is, by definition, the very opposite of a "constituent material."[18]

Thimerosal cannot be an adulterant or contaminant for yet another reason: it is an FDA-approved and licensed component of the vaccines in question. The licensed product formulation for the vaccines that use thimerosal as a preservative list it as a chemical component; the FDA reviewed and approved the product license before the vaccines could be used by doctors; and the vaccine manufacturers cannot deviate from the formulation of the vaccine as set forth in the approved product license.[19]

In contrast, adulterants and contaminants, by their very nature, cannot be "ingredients." They are present only because of such outside events as tampering, unsanitary

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[18] A "constituent" is an "essential part: component element," while, on the other hand, an "extraneous" element is one "not forming an essential or vital part." Webster's Ninth New Collegiate Dictionary.

[19] As prescription biological products, vaccines are subject to the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 77 301-307 (2000), and the Public Health Service Act, 42 U.S.C. § 262 *et seq.* (1994 and Supp. V 1999). Those statutory provisions, together with the regulations promulgated thereunder, govern nearly every aspect of vaccine testing, design, production, labeling, and distribution.. Federal law requires that biological products be licensed through the submission of a Product License Application to the FDA and also requires FDA approval of the package inserts that accompany each vaccine and enter the Physicians' Desk Reference ("PDR"). Once the FDA licenses a vaccine formula, federal regulations preclude a vaccine manufacturer from deviating from the "qualitative or quantitative formulation or other specifications as provided in the approved application" without prior FDA approval. See 21 CFR § 601.12(b)(2)(i); see also 21 CFR § 601.12 (a). The removal or replacement of a preservative in a vaccine would be a "major change" in the licensed formula and would therefore require prior FDA approval. See 21 CFR § 601.12(b)(2)(vi).

conditions, or bad manufacturing practices.[20] Thimerosal's presence in vaccines resulted not from any such outside event, but from its inclusion by the manufacturer in the FDA approved product.

The HHS Secretary, the official charged by law with the administration and interpretation of the Vaccine Act, has consistently informed the public that (i) "[c]omponents, such as thimerosal, . . . cannot and should not be considered adulterants or contaminants" and (ii) "[b]ecause thimerosal is not an adulterant to or a contaminant of vaccines, individuals who have claims relating to thimerosal in vaccines . . . must first file the claim with the [Vaccine Court] before pursuing any other civil litigation" HHS Website (Exhibit 4).

The HHS Secretary's determination has been unequivocal. In King v. Aventis Pasteur, Inc., CV 01–1305-AS (D. Ore.), one of the first cases to allege that thimerosal-containing vaccines cause neurodevelopmental injuries, the HHS Secretary took the extraordinary step of intervening to file a 22-page "Statement of Interest." In it, the HHS Secretary states why claims alleging injury due to thimerosal in vaccines are "vaccine related" and, therefore, within the Vaccine Court's exclusive jurisdiction:

> Thimerosal is neither an adulterant nor a contaminant within the Act's plain meaning or those terms' accepted definitions.
>
> Thimerosal cannot be an adulterant or contaminant when used within prescribed limits of a valid biologics license.
>
> "The legislative history supports finding that Congress intended that injuries allegedly related to thimerosal be brought under the Program."
>
> "Interpreting Thimerosal as an 'Adulterant or Contaminant' Undercuts the Comprehensive Regulatory Scheme Established by Congress to Both Promote the Public Health by Ensuring the Vaccine Supply and Compensate Vaccine-Related Injuries."

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20 See 21 U.S.C. § 351 (defining the conditions that make a drug "adulterated" within the meaning of the Federal Food, Drug, and Cosmetic Act).

> The linchpin of Plaintiffs' argument is their ***erroneous*** assertion that thimerosal, used as a preservative in vaccines, is an "adulterant" or "contaminant." Plaintiffs' argument is merely an attempt to evade the statutory bar on civil actions against manufacturers and administrators of vaccines for vaccine-related injuries unless a claimant has first filed a timely petition in the Court of Federal Claims.
>
> Plaintiffs' argument, if successful, would contravene the purpose of the [Vaccine] Act and would substantially undermine its goals.
>
> [Plaintiffs'] complaint should be dismissed against the defendant vaccine manufacturers and administrators to the extent that the putative class members seek damages for injuries resulting from vaccines covered by the Program. ***Plaintiffs cannot avoid the exclusive jurisdiction of the Court of Federal Claims and the procedures of the Program by erroneously arguing that thimerosal is an adulterant or contaminant.*** The plain language of the statute and the determinations that have been made by the Secretary demonstrate that ***their argument is fundamentally incorrect and without merit***.[21]

The HHS Secretary's interpretation is not only entitled to deference but is controlling. The agency's interpretation of the statute it is charged with enforcing is entitled to great deference (Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843 (1984); see also C. K. v. New Jersey Dept. of Health & Human Servs., 92 F.3d 171, 181 (3d Cir. 1996); Advanced Career Training v. Riley, 1997 WL 214863 (E.D. Pa.)) and is ***controlling*** unless clearly erroneous. Auer v. Robbins, 519 U.S. 452, 461 (1997) (agency's interpretation of its own regulations is controlling unless clearly erroneous); Navellier v. Sletten, 262 F.3d 923, 945 (9th Cir. 2001) ([A]n agency's "reasonable interpretation of a statute it administers, including its promulgation of rules and regulations interpreting or implementing the statute, is entitled to deference" . . . and 'an agency's interpretation of one of its rules, including an interpretation expressed in an amicus brief is ***controlling*** unless plainly erroneous or inconsistent with the rule.") (emphasis added)). Here, all the preconditions for according the HHS Secretary's determination controlling weight are present: the HHS Secretary has interpreted (i) the statute it

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21 Statement of Interest (Exhibit 1) at 2-3, 9-13, 20-21 (emphasis added).

administers, (ii) in a manner consistent with a 30-year-old regulation promulgated pursuant to notice-and-comment rulemaking, and (iii) expressed the interpretation by posting it publicly as well as by *amicus* brief. Plaintiffs do not even contend that the HHS Secretary's interpretation is clearly erroneous. Deference is particularly appropriate here, because "Congress delegated ***unusually great authority*** to the Secretary" under the Vaccine Act, including the power to rewrite the Act by classifying vaccines into certain categories. O'Connell, 79 F.3d at 180 (emphasis added).[22]

Even if the HHS Secretary had never spoken to the issue, the law would still be clear that the Act applies, for the Vaccine Court itself has consistently interpreted the Act to apply to claims concerning vaccine components. Early in the life of the Act, the Federal Circuit affirmed an award under the Vaccine Act where the claim was, as here, that the vaccine was injurious by reason of the preservative. Grant v. Sec'y, Dep't of Health & Human Servs., 956 F.2d 1144, 1149-50 (Fed. Cir. 1992). Three years later, the Federal Court of Claims defined a "vaccine-related injury" to be one "caused by the vaccine ***or by something contained therein***." Pannell v. Sec'y, Dep't of Health & Human Servs., No. 94-658V, 1995 WL 432643, at *2 (Fed.

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22 Plaintiffs argue that the sovereign immunity doctrine dictates that the Vaccine Act be narrowly construed. But, they cannot invoke the sovereign immunity doctrine and then disregard what the sovereign says. What plaintiffs fail to appreciate is that sovereign immunity is a defense that must be raised by the government. The sovereign immunity doctrine, in other words, belongs to the sovereign and must be invoked by the sovereign. This is true whether the sovereign is the United States of America, Perry v. United States, 936 F. Supp. 867, 879 (S.D. Ala. 1996), one of the fifty states, Wis. Dep't of Corrections v. Schacht, 524 U.S. 381, 389 (1998), or a foreign nation, Aquamar S.A. v. Del Monte Fresh Produce N.A., 179 F.3d 1279, 1290 (11th Cir. 1999). To be sure, the Vaccine Court has applied the sovereign immunity doctrine to Vaccine Act cases on numerous occasions. See Burch v. Secretary of HHS, No. 99-946V, WL 180129, at *4 (Fed. Cl. Feb. 8, 2001). It has done so, however, only at the behest of the government, when it argues the doctrine applies. See id. (citing 35 cases). Conversely, when the government waives sovereign immunity or concedes that a federal statute applies, the doctrine does not come into play. Here, the sovereign has spoken and said that the Vaccine Act applies.

Cl. July 7, 1995) (emphasis added) (copy attached as Exhibit 7). And even more recently, speaking specifically of the "chemical/biological components" of the vaccine, the Vaccine Court held that whether the Act applied turned on whether there was "direct exposure to the vaccine components." That is, when the "chemical/biological components" of the vaccine "enter into the body of" the plaintiff, he has a claim under the Vaccine Act. Brausewetter v. Sec'y of Health & Human Servs., No. 99-278V, 1999 WL 562700, at *3 (Fed. Cl. July 16, 1999) (copy attached as Exhibit 8).[23]

It is not surprising, therefore, that the Vaccine Court is currently exercising jurisdiction over many cases that allege injury due to the thimerosal in vaccines. The Court has always held that the Act covers claims concerning vaccine components, specifically preservatives. What ***is*** surprising is plaintiffs' argument that a Pennsylvania state court could reasonably conclude that the Vaccine Court will not exercise jurisdiction over these claims when it is, in fact, already doing so.

The only court to rule whether the Vaccine Act controls claims for thimerosal-related injuries issued four separate decisions holding either directly or implicitly that the Act does so control. O'Connell, *supra*; Blackmon, *supra*; Owens, *supra*; Strauss, *supra*.[24] In each of these cases, the United States District Court for the Southern District of Texas

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[23] Plaintiffs cite Brausewetter, but miss the point of the case. Its reasoning refutes plaintiffs' argument for two reasons. First, it recognizes that the term "vaccine" is not synonymous with the toxoid (i.e., the "biological" component that is capable of stimulating antitoxin antibodies), but also includes all the components that make up the preparation that is injected, including "chemical components" like thimerosal. Second, Brausewetter makes clear that exposure to a vaccine means exposure to its chemical/biological "components."

[24] Although the posture of Strauss differed from the other three cases in that the parent-plaintiffs purportedly brought claims only on their own behalf, the court again held that the Vaccine Act applied to claims concerning thimerosal-containing vaccines. In Strauss, the court dismissed the parents' derivative consortium claims with prejudice since it was clear from the face of the pleadings that the primary injury claims of the child from which the consortium claims depend were barred by the Vaccine Act's statute of limitations. Strauss at 7-9 (Exhibit 6).

considered allegations and arguments virtually identical to those presented here, i.e., the plaintiffs claimed neurological injuries allegedly caused by thimerosal in childhood vaccines. And the district court held that "***the language of the Vaccine Act unambiguously and specifically indicates that injuries caused by vaccines preservatives (i.e. thimerosal) are within its scope***, [and] ***it is clear that Congress has spoken to the precise question at issue.***" Owens at 9, n.11 (Exhibit 5).[25]

In reaching this conclusion, the court recognized that "***neither the plain meaning of 'adulterant' nor 'contaminant' applies to thimerosal when, as here, it is purposefully used as an ingredient in the approved formulation of a vaccine.***" Id. at 8. The court found that, as an FDA-approved preservative, thimerosal is a "constituent material" of vaccines[26] that "maintain[s] [their] safety, purity and potency"—and is thus the very opposite of an adulterant or contaminant:

> In fact, thimerosal has been widely used as a vaccine preservative since the 1930's . . . and its use satisfies the FDA's requirement that preservatives be added to vaccines distributed in multi-use vials. . . . ***As such, thimerosal cannot be said to "make impure or corrupt" a vaccine or to reduce a vaccine's therapeutic value. Furthermore, thimerosal cannot be characterized as having an undesirable effect or diluting the active material found within a vaccine. In fact, the precise opposite is true. As a preservative, thimerosal prevents a vaccine's corruption.***

Id. at 7-8 (emphasis added) (citations omitted).

Having found the "adulterant or contaminant" exception inapplicable to the preservative thimerosal, the court reasoned that the Vaccine Act's definition of "vaccine-related injury" clearly includes claims for thimerosal-related injuries:

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25 Even had the court not found such a clear expression of Congressional intent, it "would have adopted the position taken by the Secretary of the Department of Health and Human Services" as a matter of judicial deference. Id.

26 Id. at 8 n.10 ("The FDA has long recognized that preservatives (i.e., thimerosal) are 'constituent materials' of vaccines.") (citing 21 C.F.R. § 610.15).

> [T]he language used by Congress to define "vaccine-related injury" (i.e. "associated with one or more . . . vaccines") likewise requires a finding that the [plaintiffs' claims] are covered by the Program. . . . [A] vaccine is a "suspension" or "preparation" composed of both microorganisms ***and additional ingredients***. And, as explained above, manufacturers of vaccines add thimerosal to the "preparation" or "suspension" of vaccines. Therefore, ***because the children's injuries are allegedly linked to a vaccine ingredient, their injuries are definitely "vaccine-related."***

Id. at 8-9 (emphasis added) (footnotes omitted) (citing Pannell, Brausewetter, and Grant).

Thus, finding that the plaintiffs' alleged injuries "***cannot be 'thimerosal-related' without being 'vaccine-related' as well***," the court dismissed the plaintiffs' claims for failure to first file a petition in the Vaccine Court.[27] Owens at 9 (Exhibit 5). The federal court in Demos v. Aventis Pasteur, Case No. 01-04504-CIV-Graham (S.D. Fla. Mar. 21, 2002) (copy attached as Exhibit 9), came to the same clear-cut conclusion, albeit *in dicta*:

> It appears that in light of the agency's interpretation, ***which must be accorded deference unless plainly erroneous***, and the Court of Federal Claims' assertion of jurisdiction over thimerosal-related claims, ***persons who have suffered thimerosal-related injuries must first file a petition in the Court of Federal Claims, and both state and federal courts faced with such claims have the same obligation under federal law to dismiss those claims if a petition has not been first filed in the Court of Federal Claims***.[28]

See also McDonald v. Abbott Laboratories, Inc., C.A. No. 02CV77LN (S.D. Miss. June 21, 2002) (defendants unquestionably have the better of the argument on the issue of whether injuries alleged to have resulted from thimerosal in vaccines constitute vaccine-related injuries under the Vaccine Act").

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27 The district court also dismissed the parent plaintiffs' claims for loss of services and emotional distress, but found that the petition stated a viable claim for loss of consortium under Texas law. Owens at 11-13 (Exhibit 5). In its subsequent Strauss decision, the court held that the derivative claims of the parents are subject to the same limitations period under the Vaccine Act as the primary claims of the child. Strauss at 8-9 (Exhibit 6).

28 Id. at 11-12 (emphasis added). The court remanded in Demos because it could not say that the parental consortium claims failed to state a cause of action under Florida law and, therefore, were fraudulently joined.

Plaintiffs set in the balance three decisions remanding similar cases, King, et al. v. Aventis Pasteur, et al., No. CV 01-1305-BR (D. Ore. June 7, 2002), Doherty, et al. v. Aventis Pasteur, et al., No. C01-4771 MJJ (N.D. Cal. May 17, 2002), and Garcia, et al. v. Aventis Pasteur, et al., No. C02-0168C (W.D. Wash. Apr. 22, 2002) (Pl. Mem. at 6, 14). These decisions lack any persuasive force, however, for they fail to distinguish -- indeed, fail to address -- the authority cited above. They obviously fail to accord the HHS Secretary's determination controlling deference, but fail even to acknowledge the rule of judicial deference. Moreover, they fail to consider: (1) 21 C.F.R. § 610.15, defining vaccine preservatives as "constituent materials;" (2) the Amendola decision, defining adulterants and contaminants as "extraneous" materials; (3) the consistent line of authority in the Vaccine Court, from Grant to Pannell to Brausewetter, holding that the Vaccine Act reaches claims concerning vaccine components, including preservatives; (4) the fact that thimerosal is an FDA-approved ingredient of the vaccines in question, listed as such in the Physicians Desk Reference, and not a substance that found its way into vaccines by tampering or mishap in the manufacturing process; and (5) the further fact that the Vaccine Court is presently exercising jurisdiction over just these claims, advising by order in June that it is establishing a schedule to "resolve" the claims. If a candidate for the bar exam were not to address this many points in an essay answer, he would not be practicing law.[29]

In sum, plaintiffs contention that thimerosal is an "adulterant" or "contaminant," thereby removing this case from the reach of the Vaccine Act, is frivolous.

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[29] In Garcia and Doherty, the courts devoted almost all their discussion to whether removal was proper on "federal question" grounds -- an issue not present in this case. In King, the decision turned on the technical question whether the Vaccine Act is an "extraneous" defense under Oregon procedure -- also an issue not present in this case.

B. The Vaccine Act Applies To Claims For The Child's Medical Expenses Brought By The Parents

Plaintiffs further attempt to circumvent the Act by arguing that the Parents' claims for medical expenses incurred on behalf of their son are not included within the scope of the Act, despite the clear statutory provisions to the contrary. The Act identifies a party authorized to bring a petition in Vaccine Court as "any person who has sustained a vaccine-related injury [or] ***the legal representative of such person if such person is a minor*** or is disabled. . . ." 42 U.S.C. § 300aa-11(b)(1)(A) (emphasis added). And the Act provides that the compensation awarded "shall include" medical expenses incurred on behalf of the injured person. 42 U.S.C. § 300aa-15(a). There is no question that the medical expenses sought by plaintiffs are "traceable to vaccinations;" a simple review of the Complaint confirms that this is so. Complaint at ¶ 94. Thus, because the Act provides for—and indeed mandates—compensation for medical expenses incurred by or on behalf of the injured person, the Act governs the claims by plaintiff parents for medical expenses incurred on their child's behalf and requires that these claims be dismissed outright.

Plaintiffs acknowledge that the Act has been interpreted not to bar family members from bringing a tort action for compensation "for their ***own*** related injuries, such a[s] loss of companionship or consortium." Pl. Mem. at 18 (emphasis added). However, plaintiffs' Complaint makes no claim for loss of companionship or loss of consortium. Rather, plaintiffs are seeking the very medical expenses which are expressly covered by the Act.

As the Strauss court explained, holding that just such parent claims are barred by the Act:

> [A]lthough Plaintiffs are not barred outright by the Vaccine Act from seeking individual damages (*i.e.*, loss of consortium) from the Vaccine Manufacturers, ***they cannot recover from the Vaccine Manufacturers for any expenses that they have incurred on [the minor child's] behalf.*** As explained above, the Vaccine Act provides compensation for actual and un-reimbursable expenses and projected expenses (incurred by the victim or on the victim's behalf) for medical or other remedial care determined to be reasonably necessary, actual and anticipated lost earnings, actual and projected pain and suffering of the victim and reasonable

> attorneys' fees and costs. ***The covered expenses include those costs which "have been or will be incurred by or on behalf of the [victim]*** . . . for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and services expenses, and the facilities determined to be reasonably necessary."

Id. (emphasis added) (quoting 42 U.S.C. § 300aa-15(a)(1)).

This analysis is consistent with the First Circuit's decision in Schafer, which permitted certain family members' suit to go forward "to recover their own damages," but, in doing so, described the litmus test that distinguishes between the indirect damages that are the family members' own (and thus outside of the Vaccine Act's application) and the direct damages of the person affected by the vaccine (and thus covered by the Act). As the Schafer court drew the line: "the Act sees the tort suit procedural bar and Vaccine Court compensation . . . as opposite sides of the same coin." 20 F.3d at 5. Thus, "if [the plaintiff] cannot file a petition with the Vaccine Court, the Act says that its tort suit ban does not apply to him." Id. Conversely, if the plaintiff ***can*** file a vaccine petition, the tort suit ban ***does apply***.[30] Indeed, allowing claims

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30 On appeal from a Vaccine Court decision, the Federal Circuit in Abbott v. HHS, 1994 U.S. App. LEXIS 2459 (Fed. Cir. Feb. 7, 1994) made the same distinction. Plaintiffs cite Abbott for the proposition that a parent can bring an independent claim for loss of consortium -- a proposition that is irrelevant here -- and fail to appreciate that the case makes clear that a parent cannot maintain an independent claim for the child's medical expenses, which is what plaintiffs here are attempting to do. In deciding that the mother's prior wrongful death state court suit did not seek damages available to the child under the Vaccine Act, but that the survival action concerned damages available in the Vaccine Court, the Federal Circuit explained: "The critical determination is ***not the identity of the parties in the state action, however, but rather, the nature of the damages obtained***." 1994 U.S. App. LEXIS 2459 at *12 (emphasis added). Put another way, any "costs incurred by or on behalf of the injured party due to the vaccine-related injury, including 'diagnosis and medical or other remedial care determined to be reasonably necessary' . . . [are] those of the child, ***whether the costs are actually incurred by the child or by someone else on behalf of the child***." Id. at *14 (emphasis added) (quoting 42 U.S.C. § 300aa-15(a)(iii)(I) and (II)).

Cook v. Children's Medical Group, P.A., 756 So.2d 734 (Miss. 1999), is not to the contrary. The court in Cook held that the parents could pursue a claim for the child's expenses, but only because the parents' claim was grounded in fraud -- that is, the parents were

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that are compensable under the Act to go forward in a judicial forum—simply because they are pled by the parents rather than the child—"would clearly undermine the stated objectives of the Vaccine Act." Strauss (Exhibit 6) at 6, n.8. Here, the plaintiff parents had the opportunity to file a petition for compensation on behalf of their child. Their claims for any and all medical care and expenses necessitated by the child's condition are costs actually incurred either "by or on behalf of" the child, are compensable under the Vaccine Act, and thus fall squarely within the Act's tort suit ban and should be dismissed.

C. Plaintiffs Are Qualified To File A Claim Under The Vaccine Act

Plaintiffs' final argument to evade the reach of the Vaccine Act is equally devoid of merit. The remedial system for vaccine injuries would hardly achieve its laudable goals if the system was merely optional or avoidable. Thus, Congress prohibited anyone from bypassing the Vaccine Act:

> ***No person*** may bring a civil action for damages in an amount greater than $1,000 . . . against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury . . . ***unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury. . . .***

42 U.S.C. § 300aa-11(a)(2)(A) (emphasis added). The plaintiffs here assert that they can never comply with the requirement of first bringing their claims in Vaccine Court, because those claims are barred by the Vaccine Act's limitations provision (§ 300aa-16(2)).

Not being able to meet the prerequisite of filing their claims first in Vaccine Court, the plaintiffs have no chance to prevail against the non-diverse defendants in state court.

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allowed to seek recovery of the compensation that they could have ***received in the Vaccine Court by filing a petition for compensation*** but for the fraud of the doctors who allegedly prevented them from timely filing a petition.

That is the express holding both in McDonald v. Lederle Laboratories, 775 A.2d 528 (N.J. Super. 2001), and the June 11, 2002 order of the United States District Court for the Southern District of Texas in Strauss:

> This Court concurs with the New Jersey Supreme Court's recent determination that "[t]he plain meaning of the [Vaccine] Act and the Congressional intent are consistent with the conclusion that failure to file a timely petition under the Program bars the later pursuit of a State tort action through the Program's election procedure."

Strauss, *supra*, Order at 8 (June 11, 2002) (quoting McDonald, 775 A.2d at 532) (attached as Exhibit 6). The same result was reached in Walton v. Lederle Laboratories, No. 3:99-CV-747 (S.D. Miss. Sept. 28, 2001) (attached as Exhibit 10).[31]

To avoid diversity jurisdiction, the plaintiffs engage in strained statutory interpretation. According to the plaintiffs, they lack qualifications or standing to file vaccine-related claims because they did not file those claims within the Vaccine Act's limitations period. See Pl. Mem. at 7-8. As a supposed consequence of their lack of standing, the plaintiffs contend that they are immune from the requirement of first filing their claims in Vaccine Court. See id.

The plaintiffs contend that the requirement of first filing a claim with the Vaccine Court applies only to those "qualified to file a petition" in section 300aa-11(a)(9) of the Vaccine Act. They then argue that when, as here, the three-year limitations period in section 300aa-16(a)(2) has expired, a person is not "qualified" to file and, supposedly, the first-file requirement does not apply.

That syllogism is incorrect, first of all, because it improperly melds standing with limitations. Limitations and standing are separate issues. See, e.g., In re Lorazepam &

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[31] While Walton applied the two-year limitations provision for wrongful death claims and did not concern thimerosal, the court held that a plaintiff may not sue in any court if a timely claim was not filed in Vaccine Court.

Clorazepate Antitrust Litig., 289 F.3d 98, 108 (D.C. Cir. 2002) (describing limitation as a threshold issue and standing as a jurisdictional issue); Rozema v. Marshfield Clinic, 174 F.R.D. 425, 444 (W.D. Wis. 1997) (listing limitations and standing as separate affirmative defenses). It is no surprise, then, that the plaintiffs can cite no authority for their novel theory.

The plaintiffs' arguments also fail because they conflict with the purpose and language of the Vaccine Act. Indeed, the plaintiffs do not even attempt to address the clear congressional intent that all vaccine-injuries must be presented first, **if at all**, in the Vaccine Court.[32] Instead, they rely on contorted statutory interpretation.

What the Vaccine Act plainly means is the opposite of what the plaintiffs contend. In order to be "qualified to file a petition for compensation " (i.e., to have standing) under the Vaccine Act, a person must fall within the class of "petitioners" defined by section 300aa-11(b)(1)(A). "Petitioners" are defined by that section as those who have sustained a vaccine-related injury, or their legal representatives in the case of a minor, a disabled person, or a deceased person. See Owens, *supra*, noting that an "individual becomes eligible to file a petition [in the Vaccine Court] if he or she suffers a specified injury after receiving a vaccine." Separate from that description of "qualified" "petitioners," section 300a-11(a)(2)(A) states that a petition must be filed in accord with section 300aa-16. Section 300aa-16 has nothing whatsoever to do with qualifications or standing of "petitioners," but merely sets the deadline for a qualified person to file his or her claim.

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[32] The legislative history confirms the Act's plain meaning, showing that Congress intended that claimants must first seek redress under the Act: "*All individuals* injured by a vaccine administered after the date of enactment of the legislation are required to go through the compensation program" before proceeding with *any* litigation against a manufacturer. H.R. Rep. No. 99-9080 at 3, reprinted in 1986 U.S.C.C.A.N. at 6344 (emphasis added). The courts have strictly applied the letter and intent of § 300aa-11(a)(2)(B). See, e.g., Brown v. Sec'y of Health & Human Servs., 874 F. Supp. 238, 241 (S.D. Ind. 1994), aff'd mem., 61 F.3d 905 (7th Cir. 1995) (dismissing vaccine case because the plaintiffs had not first filed a petition under the Vaccine Act).

This Court should accept the Vaccine Act's plain meaning. No person can file a suit in state or federal court without first seeking redress in the Vaccine Court. If the limitations provision bars a claim in the Vaccine Court, then no claim can be filed anywhere, as was held both in McDonald, 775 A.2d at 532, Strauss (Exhibit 6), and Walton (Exhibit 10). To hold otherwise would allow those claiming vaccine-related injuries to sidestep the Vaccine Act merely by delaying their claim.

IV. CONCLUSION

This Court has original jurisdiction in this case pursuant to 28 U.S.C. § 1332. Plaintiffs have not and cannot assert a remotely colorable cause of action against the non-diverse vaccine supplier defendants in light of the unambiguous terms of the Vaccine Act. Complete diversity of citizenship therefore exists and the amount in controversy exceeds the jurisdictional threshold. Furthermore, defendants' removal of this action was timely, proper, and complies with 28 U.S.C. §§ 1441 and 1446. Plaintiffs' Motion for Remand should therefore be denied.

Respectfully submitted,

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DATED: July 3, 2002

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Defendants' Opposition To Plaintiffs' Motion For Remand has been served via first-class mail, postage prepaid, this 3rd day of July, 2002, upon all counsel on the attached Service List.

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MICHAEL T. SCOTT